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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/840,037	05/06/2004	Klaus Fuchs	1/1497	7763

28501 7590 08/23/2005

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EXAMINER

HEARD, THOMAS SWEENEY

ART UNIT PAPER NUMBER

1654

DATE MAILED: 08/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

10/840,037

Applicant(s)

FUCHS ET AL.

Examiner

Thomas S. Heard

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1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 2-4 and 6-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/12/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-14 in the reply filed on June 10, 2005 is acknowledged. Applicants have further elected compound No. 14 of Table 1 in the specification on page 35.

Claims 15-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected subject matter, there being no allowable generic or linking claim.

The applicant's elected species has been found free of the art. The Examiner has found art related subject matter and a 35 USC 102(b) rejection has been applied, see below under Claim Rejections 35 USC § 102. Claims 2-4 and 6-14 are withdrawn as they do not read on the Examiner's art disclosed species.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

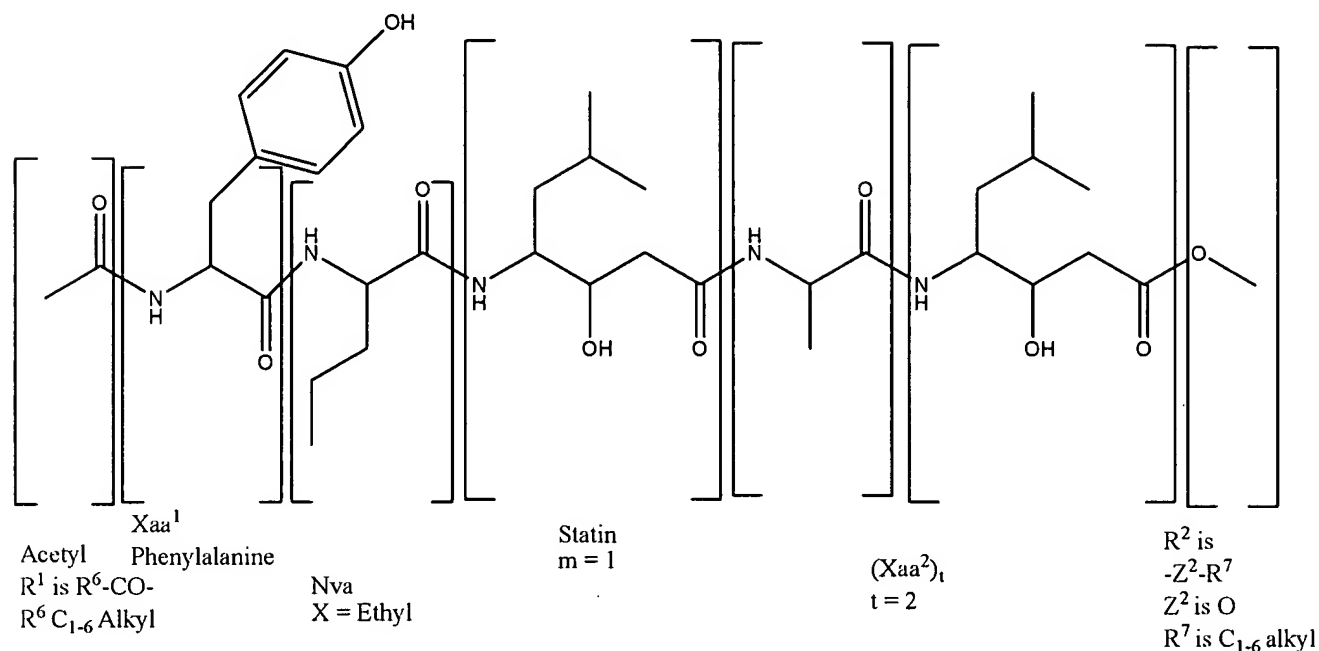
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Guegan, R., et al, "Pepstatin analogues as novel rennin inhibitors," 1986, Jul;29(7):1152-1159. Guegan, R., et al discloses compound No. 25 in Table 1 on page

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1153 readable upon claims 1 and 5. Guegan, R., et al discloses compounds of the formula A-X-Y-Sta-Ala-Sta-R:



The instantly claimed invention is therefore anticipated.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Cronshaw RF, Schauer-Vukasinovic V, Powell DJ, Giller T, Bur D, Kay J. "Inhibition of human napsin A." Protein Pept Lett. 2003 Feb;10(1):35-42.

Kuzmic, Petr; Sun, Chong Qing; et al "Long Range Electrostatic Effects in Pepsin Catalysis" Tetrahedron (1991) 47(14-15), 2519-2534

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Poe, Martine et al "Interaction of mouse submaxillary gland renin with a statine-containing, subnanomolar, competitive inhibitor" Journal of Enzyme Inhibition (1985), 1(1), 13-23

Rich, Daniel H et al "Synthesis of analogs of Pepstatin Journal of Medicinal Chemistry" (1983), 26(6), 904-910.

Hui KY, Holtzman EJ, Quinones MA, Hollenberg NK, Haber E. "Design of rat renin inhibitory peptides." J Med Chem. 1988 Sep;31(9):1679-86.

Nisato D, Wagnon J, Callet G, Mettefeu D, Assens JL, Plouzane C, Tonnerre B, Pliska V, Fauchere JL. « Renin inhibitors. Free-Wilson and correlation analysis of the inhibitory potency of a series of pepstatin analogues on plasma renin." J Med Chem. 1987 Dec;30(12):2287-91.

Tung, Jay S., et al, ' Design of Substrate-based inhibitors of Human-beta-secretase," J. Med. Chem (2002), Vol. 45, 259-262.

Applicant's should note that in claims 10 and 11; Colostrinin is a Trademark and would have been rejected under 35 USC 112 2nd were the claims not withdrawn from consideration.

Conclusions

The Applicant's elected species is free of the prior art.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas S. Heard whose telephone number is (571) 272-2064. The examiner can normally be reached on 9:00 a.m. to 6:30 p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TSH

A handwritten signature in black ink that reads "Bruce Campell". The signature is written in a cursive, flowing style.

BRUCE R. CAMPPELL, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600